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Erythromycin Stearate

$C_{37}H_{67}NO_{13} \cdot C_{18}H_{36}O_2$ 1018.40

Erythromycin octadecanoate (salt);

Erythromycin stearate (salt) CAS RN®: 643-22-1; UNII: LXW024X05M.

DEFINITION

Erythromycin Stearate is the stearic acid salt of Erythromycin, with an excess of Stearic Acid. The sum of the percentages of erythromycin A, erythromycin B, and erythromycin C is NLT 55.0%, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** (USP 1-Dec-2019) **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197M** (CN 1-MAY-2020)

Add the following:

- **B.** The retention times of the erythromycin A, erythromycin B, and erythromycin C peaks in the *Sample solution* correspond to those of *Standard solution 2*, as obtained in the Assay. (USP 1-Dec-2019)

ASSAY

Change to read:

PROCEDURE

▲ Use solutions containing erythromycin promptly, or within 1 day if stored in a refrigerator. (USP 1-Dec-2019)

Diluted phosphoric acid: Dilute 10 mL of [phosphoric acid](#) with [water](#) to 100 mL.

Solution A: 20 mg/mL of [dibasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 8.0.

Solution B: 35 mg/mL of [dibasic potassium phosphate](#) in [water](#). Adjust with [potassium hydroxide TS](#) or *Diluted phosphoric acid*, as appropriate, to a pH of 9.0.

Solution C: 20 mL of *Solution A*. Adjust with [phosphoric acid](#) to a pH of 3.5.

Mobile phase: [Acetonitrile](#), [tertiary butyl alcohol](#), *Solution B*, and [water](#) (6:35:10:149)

Standard solution 1: 40 mg of [USP Erythromycin RS](#) in a conical flask. Add 5.0 mL of [methanol](#), and swirl to dissolve. Add 5.0 mL of *Solution A*.

Standard solution 2: 6 mg each of [USP Erythromycin RS](#), [USP Erythromycin B RS](#), [USP Erythromycin C RS](#), and [USP Erythromycin Related Compound N RS](#) in a 50-mL conical flask. Add 15.0 mL of [methanol](#) and swirl to dissolve. Add 15.0 mL of *Solution A*.

▲ (USP 1-Dec-2019)

Sample solution: 165 mg of Erythromycin Stearate in a 100-mL conical flask. Add 15.0 mL of [methanol](#) and swirl to dissolve. Add 15.0 mL of *Solution A* and mix. Allow the resulting suspension to settle, and pass a portion of the supernatant through a filter of 0.2-µm or finer pore size. Use the clear filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; packing [L21](#) (1000Å)

Column temperature: 70°

Flow rate: 2 mL/min

Injection volume: 100 µL

Run time: NLT 5 times the retention time of erythromycin A

System suitability

Samples: *Standard solution 1* and *Standard solution 2*

The elution order of the components is erythromycin related compound N, erythromycin C, erythromycin A, and erythromycin B.

Suitability requirements

Resolution: NLT 0.8 between erythromycin related compound N and erythromycin C; NLT 5.5 between erythromycin related compound N and erythromycin A, *Standard solution 2*

Relative standard deviation: NMT 2.0%, *Standard solution 1*

Analysis

Samples: *Standard solution 1, Standard solution 2, ▲▲ (USP 1-Dec-2019) and Sample solution*

▲▲ (USP 1-Dec-2019)

Calculate the percentage of erythromycin A in the portion of Erythromycin Stearate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100$$

r_U = peak response of erythromycin A from the *Sample solution*

r_S = peak response of erythromycin A from *Standard solution 1*

C_S = concentration of [USP Erythromycin RS](#) in *Standard solution 1* (mg/mL)

C_U = concentration of Erythromycin Stearate in the *Sample solution* (mg/mL)

P = percentage of erythromycin A in [USP Erythromycin RS](#)

Calculate the percentage of erythromycin B and erythromycin C in the portion of Erythromycin Stearate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100$$

r_U = peak response of the relevant analyte from the *Sample solution*

r_S = peak response of the relevant analyte from *Standard solution 2*

C_S = concentration of the corresponding Reference Standard in *Standard solution 2* (mg/mL)

C_U = concentration of Erythromycin Stearate in the *Sample solution* (mg/mL)

P = ▲potency of erythromycin B or erythromycin C in the corresponding Reference Standard (mg/mg)▲ (USP 1-Dec-2019)

Acceptance criteria: The sum of the percentages of erythromycin A, erythromycin B, and erythromycin C is NLT 55.0% on the anhydrous basis. The percentage of erythromycin B is NMT 12.0%, and the percentage of erythromycin C is NMT 5.0%.

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: The charred residue is moistened with 2 mL of [nitric acid](#) and 5 drops of [sulfuric acid](#).

Acceptance criteria: NMT 1.0%

Change to read:

• **ORGANIC IMPURITIES**

Diluted phosphoric acid, Solution A, Solution B, Solution C, Mobile phase, Standard solution 2, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

▲**Peak identification solution:** 5 mg of [USP Erythromycin RS](#) in 1 mL of [methanol](#). Add 5 mL of *Solution C*, mix, and allow to stand for about 30 min.▲ (USP 1-Dec-2019)

Analysis

Samples: *Standard solution 2, Sample solution, and ▲Peak identification solution*

Identify the erythromycin A enol ether peak using the *Peak identification solution*.▲ (USP 1-Dec-2019)

Calculate the percentage of the largest single impurity (the largest peak other than erythromycin A, erythromycin B, erythromycin C, erythromycin A enol ether, erythromycin *N*-ethylsuccinate, and pseudoerythromycin A enol ether) in the portion of Erythromycin Stearate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100$$

r_U = peak response of the largest single impurity (the largest peak other than erythromycin A, erythromycin B, erythromycin C, erythromycin A enol ether, erythromycin *N*-ethylsuccinate, and pseudoerythromycin A enol ether) from the *Sample solution*

r_S = peak response of erythromycin A from *Standard solution 2*

C_S = concentration of [USP Erythromycin RS](#) in *Standard solution 2* (mg/mL)

C_U = concentration of Erythromycin Stearate in the *Sample solution* (mg/mL)

P = percentage of erythromycin A in [USP Erythromycin RS](#)

Calculate the percentage of erythromycin A enol ether in the portion of Erythromycin Stearate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times (1/F) \times 100$$

